DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-24-0666]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "National Healthcare Safety Network (NHSN)" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on August 21, 2023 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Healthcare Safety Network (NHSN) (OMB Control No. 0920-0666, Exp. 6/30/2026) - Revision – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Healthcare Quality Promotion (DHQP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC) collects data from healthcare facilities in the National Healthcare Safety Network (NHSN) under OMB Control Number 0920-0666. During the early stages of its development, NHSN began as a voluntary surveillance system in 2005 managed by DHQP. NHSN provides facilities, states, regions, and the nation with data necessary to identify problem areas, measure the progress of prevention efforts, and ultimately eliminate healthcare-associated infections (HAIs) nationwide. NHSN allows healthcare facilities to track blood safety errors and various HAI prevention practice methods such as healthcare personnel influenza vaccine status and corresponding infection control adherence rates.

Enrollment in NHSN has continuously increased, with over 37,000 actively reporting healthcare facilities across the U.S. Of the total enrolled healthcare facilities, there are over 6,000

acute care facilities; 8,400 dialysis facilities; 600 long-term acute care facilities; 400 inpatient rehabilitation facilities; 800 inpatient psychiatric facilities; nearly 20,000 long-term care facilities; and 6,000 ambulatory surgery facilities. NHSN currently has eight components: Patient Safety (PS), Healthcare Personnel Safety (HPS), Biovigilance (BV), Long-Term Care Facility (LTCF), Outpatient Procedure (OPC), Dialysis Component, Neonatal Component, and Medication Safety Component.

Data reported under the Patient Safety Component are used to determine the magnitude of the healthcare-associated adverse events and trends in the rates of the events, in the distribution of pathogens, and in the adherence to prevention practices. Data will help detect changes in the epidemiology of adverse events resulting from new medical therapies and changing patient risks. Additionally, reported data is being used to describe the epidemiology of antimicrobial use and resistance and to better understand the relationship of antimicrobial therapy to this rising problem.

Under the Healthcare Personnel Safety Component, protocols and data on events — both positive and adverse — are used to determine: (1) the magnitude of adverse events in healthcare personnel; and (2) compliance with immunization and sharps injuries safety guidelines.

Under the Biovigilance Component, data on adverse reactions and incidents associated with blood transfusions are reported and analyzed to provide national estimates of adverse reactions and incidents.

Under the Long-Term Care Facility Component (LTCF), data is captured from skilled nursing facilities. Reporting methods under the LTCF component have been created by using forms from the PS Component as a model with modifications to specifically address the specific characteristics of LTCF residents and the unique data needs of these facilities reporting into NHSN.

The Outpatient Procedure Component (OPC) gathers data on the impact of infections and outcomes related to operative procedures performed in Ambulatory Surgery Centers (ASCs). The OPC is used to monitor two event types: Same Day Outcome Measures and Surgical Site Infections (SSIs).

The Dialysis Component offers a simplified user interface for dialysis users to streamline their data entry and analyses processes as well as provide options for expanding in the future to include dialysis surveillance in settings other than outpatient facilities.

The Neonatal Component includes one module, Late-Onset Sepsis/ Meningitis (LOS/MEN). This module will track late-onset sepsis and meningitis events in very low birthweight neonates housed in Level II/III, Level III, and Level IV nursery locations.

The Medication Safety Component tracks medication safety and adverse drug events (ADEs) that are among the most common causes of iatrogenic harm in U.S. hospitals.

NHSN has increasingly served as the operating system for HAI reporting compliance through legislation established by the states. As of March 2019, 36 states, the District of Columbia and the City of Philadelphia, Pennsylvania have opted to use NHSN as their primary system for mandated reporting. Reporting compliance is completed by healthcare facilities in their respective jurisdictions, with emphasis on those states and municipalities acquiring varying consequences for failure to use NHSN. Additionally, healthcare facilities in five U.S. territories (Puerto Rico, American Samoa, the U.S. Virgin Islands, Guam, and the Northern Mariana Islands) are voluntarily reporting to NHSN. Additional territories are projected to follow with similar use of NHSN for reporting purposes.

NHSN's data is used to aid in the tracking of HAIs and guide infection prevention activities/practices that protect patients. The Centers for Medicare and Medicaid Services (CMS) and other payers use these data to determine incentives for performance at healthcare facilities

across the US and surrounding territories, and members of the public may use some protected data to inform their selection among available providers. Each of these parties is dependent on the completeness and accuracy of the data. CDC and CMS work closely and are fully committed to ensuring complete and accurate reporting, which are critical for protecting patients and guiding national, state, and local prevention priorities. CMS collects some HAI data and healthcare personnel influenza vaccination summary data, which is done on a voluntary basis as part of its Fee-for-Service Medicare quality reporting programs, while others may report data required by a federal mandate. Facilities that fail to report quality measure data are subject to partial payment reduction in the applicable Medicare Fee-for-Service payment system. CMS links their quality reporting to payment for Medicare-eligible acute care hospitals, inpatient rehabilitation facilities, long-term acute care facilities, oncology hospitals, inpatient psychiatric facilities, dialysis facilities, and ambulatory surgery centers. Facilities report HAI data and healthcare personnel influenza vaccination summary data to CMS via NHSN as part of CMS's quality reporting programs to receive full payment. Still, many healthcare facilities, even in states without HAI reporting legislation, submit limited HAI data to NHSN voluntarily.

NHSN's data collection updates continue to support the incentive programs managed by CMS. For example, survey questions support requirements for CMS's quality reporting programs. Additionally, CDC has collaborated with CMS on a voluntary National Nursing Home Quality Collaborative, which focuses on recruiting nursing homes to report HAI data to NHSN and to retain their continued participation. The proposed changes in this new ICR include revisions to 23 existing data collection forms and nine new forms. In this Revision, CDC requests OMB approval for an estimated annual burden 1,784,296 hours.

Estimated Annualized Burden Hours

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Min./Hour 60)
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57.100 NHSN Registration Form	2,000	1	5/60
57.101 Facility Contact Information	2,000	1	10/60
57.103 Patient Safety ComponentAnnual Hospital Survey	5,311	1	135/60
57.104 NHSN Facility Administrator Change Request Form	800	1	5/60
57.105 Group Contact Information	1,000	1	5/60
57.106 Patient Safety Monthly Reporting Plan	7,821	12	15/60
57.108 Primary Bloodstream Infection (BSI)	5,775	5	39/60
57.111 Pneumonia (PNEU)	1,800	2	31/60
57.112 Ventilator-Associated Event	5463	8	29/60
57.113 Pediatric Ventilator-Associated Event (PedVAE)	334	1	31/60
57.114 Urinary Tract Infection (UTI)	6000	5	21/60
57.115 Custom Event	600	91	36/60
57.116 Denominators for Neonatal Intensive Care Unit (NICU)	1,100	12	4/60
57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC)	500	12	5/60
57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	5500	60	5/60
57.120 Surgical Site Infection (SSI)	3,800	12	36/60
57.121 Denominator for Procedure	3,800	12	10/60
57.122 HAI Progress Report State Health Department Survey	55	1	28/60
57.123 Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables	5,500	12	5/60
57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	5,500	12	5/60
57.125 Central Line Insertion Practices Adherence Monitoring	500	213	26/60
57.126 MDRO or CDI Infection Form	720	11	31/60
57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	5,500	29	15/60
57.128 Laboratory-identified MDRO or CDI Event	4800	79	21/60
57.129 Adult Sepsis	50	250	25/60
57.135 Late Onset Sepsis/ Meningitis Denominator Form: Late Onset Sepsis/ Meningitis Denominator Form: Data Table for monthly electronic upload	300	6	5/60
57.136 Late Onset Sepsis/ Meningitis Event Form: Data Table for Monthly Electronic Upload	300	6	5/60

57.137 Long-Term Care Facility Component – Annual Facility Survey	17,700	1	120/60
57.138 Laboratory-identified MDRO or CDI Event for LTCF	1,086	24	20/60
57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	1,019	12	20/60
57.140 Urinary Tract Infection (UTI) for LTCF	339	36	35/60
57.141 Monthly Reporting Plan for LTCF	1,099	12	15/60
57.142 Denominators for LTCF Locations	714	12	35/60
77.143 Prevention Process Measures Monthly Monitoring for LTCF	357	12	5/60
57.149 Weekly Healthcare Personnel Influenza Vaccination Cumulative Summary for Long- Term Care Facilities	125	52	60/60
57.150 LTAC Annual Survey	392	1	89/60
57.151 Rehab Annual Survey	1,160	1	89/60
57.200 Healthcare Personnel Safety Component Annual Facility Survey	50	1	480/60
57.204 Healthcare Worker Demographic Data	50	200	20/60
57.205 Exposure to Blood/Body Fluids	50	50	60/60
57.206 Healthcare Worker Prophylaxis/Treatment	50	30	15/60
57.207 Follow-Up Laboratory Testing	50	50	15/60
57.210 Healthcare Worker Prophylaxis/Treatment-Influenza	50	50	10/60
57.211 Weekly Healthcare Personnel Influenza Vaccination Cumulative Summary for Non- Long-Term Care Facilities	125	52	60/60
57.214 Annual Healthcare Personnel Influenza Vaccination Summary	5,000	1	120/60
57.218 Weekly Resident Influenza Vaccination Cumulative Summary for Long-Term Care Facilities	2,500	52	60/60
57.300 Hemovigilance Module Annual Survey	500	1	86/60
57.301 Hemovigilance Module Monthly Reporting Plan	500	12	60/60
57.303 Hemovigilance Module Monthly Reporting Denominators	500	12	77/60
57.305 Hemovigilance Incident	500	10	10/60
57.306 Hemovigilance Module Annual Survey - Non-acute care facility	500	1	36/60

57.307 Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction	500	4	21/60
57.308 Hemovigilance Adverse Reaction - Allergic Transfusion Reaction	500	4	21/60
57.309 Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction	500	1	21/60
57.310 Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction	500	2	21/60
57.311 Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction	500	4	21/60
57.312 Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction	500	1	21/60
57.313 Hemovigilance Adverse Reaction – Infection	500	1	21/60
57.314 Hemovigilance Adverse Reaction - Post Transfusion Purpura	500	1	21/60
57.315 Hemovigilance Adverse Reaction - Transfusion Associated Dyspnea 57.316 Hemovigilance Adverse Reaction	500	1	20/60
57.316 Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. Host Disease 57.317 Hemovigilance Adverse Reaction -	500	1	21/60
Transfusion Related Acute Lung Injury 57.318 Hemovigilance Adverse Reaction -	500	1	21/60
Transfusion Associated Circulatory Overload 57.319 Hemovigilance Adverse Reaction -	500	2	21/60
Unknown Transfusion Reaction 57.320 Hemovigilance Adverse Reaction - Other	500	1	21/60
Transfusion Reaction 57.400 Outpatient Procedure Component—	500	1	21/60
Annual Facility Survey 57.401 Outpatient Procedure Component -	350	1	10/60
Monthly Reporting Plan 57.402 Outpatient Procedure Component Same	350 50	12	40/60
Day Outcome Measures 57.403 Outpatient Procedure Component - Monthly Denominators for Same Day Outcome Measures	50	400	40/60
57.404 Outpatient Procedure Component - SSI Denominator	300	100	10/60
57.405 Outpatient Procedure Component - Surgical Site (SSI) Event	300	36	35/60
57.408 Monthly Survey Patient Days & Nurse Staffing 57.500 Outpatient Dialysis Center Practices	2500	12	60/60
Survey	7400	1	12/60
57.501 Dialysis Monthly Reporting Plan	7400	12	5/60

57.502 Dialysis Event	7400	12	15/60
57.503 Denominator for Outpatient Dialysis	7400	24	10/60
57.504 Prevention Process Measures Monthly Monitoring for Dialysis	1730	12	75/60
57.505 Dialysis Patient Influenza Vaccination	615	50	10/60
57.506 Dialysis Patient Influenza Vaccination Denominator	615	5	10/60
57.507 Home Dialysis Center Practices Survey	450	1	36/60
57.130 New Form - Patient Safety Component FHIR Measure Respiratory Pathogens Surveillance (RPS)-IT Initial Set up	5,500	1	1620/60
57.130 New Form - Patient Safety Component FHIR Measure Respiratory Pathogens Surveillance (RPS)-IT Yearly Maintenance	5,500	1	1200/60
57.130 New Form - Patient Safety Component FHIR Measure Respiratory Pathogens Surveillance (RPS)-Infection Preventionist	5,500	1	6/60
57.130 New Form - Patient Safety Component CSV Data Collection-Infection Preventionist CSV Data Collection-Infection Preventionist	5500	365	2/60
57.132 New Form - Patient Safety Component FHIR Measures-HOB, HT-CDI Modules-IT Initial Set up	5500	1	1620/60
57.132 New Form - Patient Safety Component FHIR Measures-HOB, HT-CDI Modules-IT Yearly Maintenance	5500	1	1200/60
57.132 New Form - Patient Safety Component FHIR Measures-HOB, HT-CDI Modules- Infection Preventionist	5500	6	6/60
57.133 New Form - Patient Safety Component FHIR Measures-VTE Module-IT Initial Set up	5500	1	1620/60
57.133 New Form - Patient Safety Component FHIR Measures-VTE Module-IT Yearly Maintenance	5500	1	1200/60
57.133 New Form - Patient Safety Component FHIR Measures-VTE Module- Infection Preventionist	5500	6	6/60
57.600 New Form - Neonatal Component FHIR Measure-Late Onset Sepsis Meningitis (LOSMEN) Module-IT Initial Set up	5500	1	1620/60
57.600 New Form - Neonatal Component FHIR Measure-Late Onset Sepsis Meningitis (LOSMEN) Module-IT Yearly Maintenance	5500	1	1200/60
57.600 New Form - Neonatal Component FHIR Measure-Late Onset Sepsis Meningitis (LOSMEN) Module-Infection Preventionist	5500	6	6/60

57.600 New Form - Neonatal Component Late Onset Sepsis Meningitis (LOSMEN) Module CDA Data Collection-Infection Preventionist	5500	12	2/60
57.700 New Form - Medication Safety Component FHIR Measure-Glycemic Control Module Hypoglycemia-IT Initial Set up	5500	1	1620/60
57.700 New Form - Medication Safety Component FHIR Measure-Glycemic Control Module Hypoglycemia-IT Yearly Maintenance	5500	1	1200/60
57.700 New Form - Medication Safety Component FHIR Measure-Glycemic Control Module Hypoglycemia-Infection Preventionist	5500	6	6/60
57.701 New Form - Glycemic Control Module- HYPO Annual Survey	10	1	120/60
57.144 New Form - Long Term Care Respiratory Tract Infections (RTI) Module	16,500	24	25/60
57.145 New Form - Long Term Care Antimicrobial Use (LTC-AU) Module CDA	16,500	12	5/60
New Form - Billing Code Data: 837I Upload	5500	4	5/60

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Centers for Disease Control and Prevention. [FR Doc. 2023-25156 Filed: 11/14/2023 8:45 am; Publication Date: 11/15/2023]